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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,377	11/19/2003	Norbert L. Wiech	15014.0012	5485

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WASHINGTON, DC 20036

EXAMINER
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ZUCKER, PAUL A

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/715,377

Applicant(s)

WIECH ET AL.

Examiner

Paul A. Zucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-31 is/are allowed.
- 6) ☒ Claim(s) 1-14, 19, 20 and 25 is/are rejected.
- 7) ☒ Claim(s) 15-18 and 21-24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/28/05, 1/11/05</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Specification***

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2-12 and 20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 and 20 recite structural formula containing the variable groups  $X^1$  and  $X^2$ . The variable groups  $X^1$  and  $X^2$  are undefined. It is therefore impossible to determine the intended scope of these claims. Claims 2 and 20 and their dependents are therefore rendered indefinite

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-14, 19, 20 and 25 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting sodium ion transport in an airway epithelial cell or treating lung disease using the compounds set forth in the examples

in the specification, does not reasonably provide enablement for the corresponding methods of using any arbitrary oxamide linkage-containing compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

These factors include, but are not limited to:

- a. the breadth of the claims: In the instant case the claims are extremely broad encompassing the method using any organic compound which has as part of its structural make up a oxyamide linkage. In theory this corresponds to an infinite number of compounds;
- b. the nature of the invention: The instantly claimed invention involves the control of sodium ion transport in airway epithelial cell or factors influencing various unspecified lung diseases. These methods require very specific structural features which cannot be *a priori* predicted since complex biological contexts are involved;
- c. the state of the prior art: the state of the prior art would not allow one to predict which, if any, of the infinite number of compounds could be successfully employed in the claimed methods other than those specifically set forth in the Examples in the specification;

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e. the amount of direction provided by the inventor: The inventor provide direction for the use of only 5-phenyl-2,4-pentadienoic acid, 7-phenyl-2,4,6-heptrienoic acid, SAHA and trichostatin for the treatment of COPD, asthma and bronchitis. No direction is provided for the use of any other organic compound for any other disease or condition;

f. the existence of working examples: The only working examples provided are directed to the use of 5-phenyl-2,4-pentadienoic acid, 7-phenyl-2,4,6-heptrienoic acid, SAHA and trichostatin. No guidance is provided for the selection or use of any other compound

Based upon the analysis above, the Examiner concludes that undue experimentation is required to make and use the claimed invention commensurate in scope with these claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 19, 20 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hite et al (US 5,028,629 07-1991). Hite discloses (Column 28, lines 40-45 and column 29, lines 5-20) the compounds B, F and G and their *in vitro* activity as 5-

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lipoxygenase inhibitors. Hite further discloses (Column 2, lines 1-7) their use as anti-asthmatic compounds.

5. Claims 19, 20 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Summers et al (Journal of Medicinal Chemistry, Hydroxamic Acid Inhibitors of 5-Lipoxygenase: Quantitative Structure-Activity Relationships, 1990, 33, pages 992-998). Summers discloses (Page 992, Column 1, first full paragraph) the use of 5-lipoxygenase inhibitors as therapeutic agents for the treatment of asthma. Summers discloses (Page 993, column 2, Chart II) compounds which are compounds of the instantly employed formula (I). Summers discloses (Page 994, Table I, entries 39-67) the 5-Lipoxygenase inhibitory action of these compounds.
6. Claims 1-14, 19, 20 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Zusi et al (US 4,731,382 03-1988) in view of Egan et al (American Journal of Respiratory Cell and Molecular Biology, Modulation of Ion Transport in Cultured Rabbit Tracheal Epithelium by Lipoxygenase, 1993, Metabolites, 795), pages 500-506). Zusi discloses (Column 10, lines 14-19, table I, entries 6-11) compounds of formula I and their activity as inhibitors of 5-lipoxygenase inhibitors. Zusi discloses (Column 6, lines 46-64) the utility of these compounds in the treatment of asthma and COPD. Zusi discloses (Column 11, lines 41-46) the administration of these compounds by inhalation. Egan discloses (Page 504, column 1, lines 1-26 and column 2, Figure 4) that inhibition of the lipoxygenase pathway inhibits sodium ion transport (absorption). The instantly claimed method for inhibiting sodium ion transport is therefore inherently anticipated by the methods of treatment of Zusi.

***Claim Objections***

7. Claims 15-18, 21-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Allowable Subject Matter***

8. Claims 26-31 are allowed. Claims 15-18, 21-24 are drawn to allowable subject matter. The following is a statement of reasons for the indication of allowable subject matter: The instantly claimed methods are neither disclosed nor fairly suggested by the closest prior art: Hite et al (US 5,028,629 07-1991), Summers et al (Journal of Medicinal Chemistry, Hydroxamic Acid Inhibitors of 5-Lipoxygenase: Quantitative Structure-Activity Relationships, 1990, 33, pages 992-998), Zusi et al (US 4,731,382 03-1988) and Egan et al (American Journal of Respiratory Cell and Molecular Biology, Modulation of Ion Transport in Cultured Rabbit Tracheal Epithelium by Lipoxygenase, 1993, Metabolites, 795).

***Conclusion***


9. Claims 1-31 are pending. Claims 1-14, 19, 20 and 25 are rejected Claims 15-18, 21-24 are objected to. Claims 26-31 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-2:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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